NOT FOR PUBLICATION

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

MERCK & CO., INC. and MERCK SHARP & DOHME CORP.., Plaintiffs, v. SANDOZ INC., Defendant.	Civil Action No. 10-1625 (SRC) (PS) Civil Action No. 10-2308 (SRC) (PS) **OPINION**

CHESLER, U.S.D.J.

This matter comes before the Court upon the motion by Plaintiffs Merck & Co., Inc. and Merck Sharp & Dohme Corp. (collectively, "Merck") for summary judgment, pursuant to Federal Rule of Civil Procedure 56, on Defendant's affirmative defense to infringement of patent invalidity due to obviousness. For the reasons discussed below, this Court will grant Plaintiffs' motion.

BACKGROUND

This matter involves two Hatch-Waxman actions for patent infringement. The cases have been consolidated for pretrial purposes and arise from the following facts. Briefly, Merck owns U.S. Patent No. 5,952,300 (the "'300 patent"), which is directed to compositions associated with Merck's antifungal drug Cancidas®. Defendant Sandoz, Inc. ("Sandoz") is a generic pharmaceutical manufacturer who has filed an Abbreviated New Drug Application seeking FDA approval to engage in the manufacture and sale of generic versions of Cancidas® prior to the expiration of the Merck patent.

APPLICABLE LEGAL STANDARDS

I. Summary Judgment

Summary judgment is appropriate under FED. R. CIV. P. 56(a) when the moving party demonstrates that there is no genuine issue of material fact and the evidence establishes the moving party's entitlement to judgment as a matter of law. Celotex Corp. v. Catrett, 477 U.S. 317, 322-23 (1986). A factual dispute is genuine if a reasonable jury could return a verdict for the non-movant, and it is material if, under the substantive law, it would affect the outcome of the suit. Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 248 (1986). "In considering a motion for summary judgment, a district court may not make credibility determinations or engage in any weighing of the evidence; instead, the non-moving party's evidence 'is to be believed and all justifiable inferences are to be drawn in his favor.'" Marino v. Indus. Crating Co., 358 F.3d 241, 247 (3d Cir. 2004) (quoting Anderson, 477 U.S. at 255).

"When the moving party has the burden of proof at trial, that party must show affirmatively the absence of a genuine issue of material fact: it must show that, on all the essential elements of its case on which it bears the burden of proof at trial, no reasonable jury could find for the non-moving party." In re Bressman, 327 F.3d 229, 238 (3d Cir. 2003) (quoting United States v. Four Parcels of Real Property, 941 F.2d 1428, 1438 (11th Cir. 1991)). "[W]ith respect to an issue on which the nonmoving party bears the burden of proof . . . the burden on the moving party may be discharged by 'showing' – that is, pointing out to the district court – that there is an absence of evidence to support the nonmoving party's case." Celotex, 477 U.S. at 325.

Once the moving party has satisfied its initial burden, the party opposing the motion must

establish that a genuine issue as to a material fact exists. Jersey Cent. Power & Light Co. v. Lacey Township, 772 F.2d 1103, 1109 (3d Cir. 1985). The party opposing the motion for summary judgment cannot rest on mere allegations and instead must present actual evidence that creates a genuine issue as to a material fact for trial. Anderson, 477 U.S. at 248; Siegel Transfer, Inc. v. Carrier Express, Inc., 54 F.3d 1125, 1130-31 (3d Cir. 1995). "[U]nsupported allegations . . . and pleadings are insufficient to repel summary judgment." Schoch v. First Fid. Bancorporation, 912 F.2d 654, 657 (3d Cir. 1990). "A nonmoving party has created a genuine issue of material fact if it has provided sufficient evidence to allow a jury to find in its favor at trial." Gleason v. Norwest Mortg., Inc., 243 F.3d 130, 138 (3d Cir. 2001).

If the nonmoving party has failed "to make a showing sufficient to establish the existence of an element essential to that party's case, and on which that party will bear the burden of proof at trial, . . . there can be 'no genuine issue of material fact,' since a complete failure of proof concerning an essential element of the nonmoving party's case necessarily renders all other facts immaterial." Katz v. Aetna Cas. & Sur. Co., 972 F.2d 53, 55 (3d Cir. 1992) (quoting Celotex, 477 U.S. at 322-23).

II. Patent invalidity due to obviousness

"A patent is presumed to be valid, 35 U.S.C. § 282, and this presumption can only be overcome by clear and convincing evidence to the contrary." Bristol-Myers Squibb Co. v. Ben Venue Labs., 246 F.3d 1368, 1374 (Fed. Cir. 2001) (citations omitted). The party asserting invalidity bears the burden of establishing it. 35 U.S.C. § 282. "This burden is especially difficult when . . . the infringer attempts to rely on prior art that was before the patent examiner during prosecution." Glaxo Group Ltd. v. Apotex, Inc., 376 F.3d 1339, 1348 (Fed. Cir. 2004)

(quotation omitted).

To patent an invention, the subject matter must be non-obvious:

> A patent may not be obtained . . . if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

35 U.S.C. § 103(a).

The Federal Circuit has set forth these basic principles to guide the determination of obviousness:

> Obviousness is ultimately a question of law, based on underlying factual determinations. The factual determinations that form the basis of the legal conclusion of obviousness include (1) the scope and content of the prior art; (2) the level of ordinary skill in the art; (3) the differences between the claimed invention and the prior art; and (4) evidence of secondary factors, known as objective indicia of non-obviousness.

Altana Pharma AG v. Teva Pharms. USA, Inc., 566 F.3d 999, 1007 (Fed. Cir. 2009) (citations omitted).

ANALYSIS

Plaintiff has moved for summary judgment on Defendant's affirmative defense to infringement of patent invalidity due to obviousness. The patent claims formulations of a pharmaceutical containing caspofungin. Because Defendant does not contend that a skilled artisan, prior to invention, faced with the problem of creating a caspofungin formulation for intravenous administration, would have recognized the patented formulation as the obvious solution to the problem, this case does not follow the typical approach to obviousness. Instead, because there is no dispute that experimentation and a formulation process were needed to arrive

at that solution to the problem, the decision on the instant motion turns on the question of whether the patented formulation was, from the start, obvious to try.[1] Sandoz contends, in short, that "Merck's claimed formulation is the result of routine pharmaceutical development, not invention." (Def.'s Opp. Br. 2.)

Discussion of the current law of obviousness begins with the Supreme Court's decision in KSR Int'l Co. v. Teleflex Inc., 550 U.S. 398, 416 (2007), in which it held: "The combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results."[2] This principle alone could be sufficient to decide this motion, had Sandoz pointed to evidence that the results of the development process would have been predictable to the skilled artisan, but Sandoz has not done so.

In KSR, the Supreme Court discussed the obviousness analysis in three cases and then stated:

> Following these principles may be more difficult in other cases than it is here because the claimed subject matter may involve more than the simple substitution of one known element for another or the mere application of a known technique to a piece of prior art ready for the improvement. Often, it will be necessary for a court to look to interrelated teachings of multiple patents; the effects of demands known to the design community or present in the marketplace; and the

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[1] "In a typical 'obvious to try' situation, the inventor selects a particular configuration from a broad range of possibilities suggested by the prior art and discovers that the configuration achieves significant advantages nowhere suggested in the prior art. In such cases, it is clear that the result achieved must be considered as well as the actual physical modification." Donald S. Chisum, 2-5 Chisum on Patents, § 5.04(1)(f) (2011). This is a very helpful definition, because it makes clear that it is not only the particular configuration, but the success of that configuration, that must be considered.

[2] Similarly, the Court stated: "If a person of ordinary skill can implement a predictable variation, § 103 likely bars its patentability." Id. at 417. Again, had Sandoz offered evidence that the patented formulation was a predictable variation of prior art formulations, that might have been sufficient to defeat this motion – but it has not done so.

> background knowledge possessed by a person having ordinary skill in the art, all in order to determine whether there was an apparent reason to combine the known elements in the fashion claimed by the patent at issue.

Id. at 417-418. Thus, the challenge for Sandoz is to show that there was an apparent reason to combine the known elements in the fashion claimed by the patent at issue. Again, Sandoz has not done so.

In KSR, the Supreme Court changed the law of "obvious to try:"

> The same constricted analysis led the Court of Appeals to conclude, in error, that a patent claim cannot be proved obvious merely by showing that the combination of elements was '[o]bvious to try.' When there is a design need or market pressure to solve a problem and there are a finite number of identified, predictable solutions, a person of ordinary skill has good reason to pursue the known options within his or her technical grasp. If this leads to the anticipated success, it is likely the product not of innovation but of ordinary skill and common sense. In that instance the fact that a combination was obvious to try might show that it was obvious under § 103.

Id. at 421 (citations omitted). Following KSR, it is possible to prove obviousness by showing that a combination was obvious to try.

In Bayer Schering Pharma AG v. Barr Labs., Inc., 575 F.3d 1341, 1347 (Fed. Cir. 2009), the Federal Circuit clarified the law of "obvious to try:"

> *O'Farrell* observed that most inventions that are obvious were also obvious to try, but found two classes where that rule of thumb did not obtain.
>
> First, an invention would not have been obvious to try when the inventor would have had to try all possibilities in a field unreduced by direction of the prior art. When what would have been 'obvious to try' would have been to vary all parameters or try each of numerous possible choices until one possibly arrived at a successful result, where the prior art gave either no indication of which parameters were critical or no direction as to which of many possible choices is likely to be successful an invention would not have been obvious. This is another way to express the *KSR* prong requiring the field of search to be among a "finite number of identified" solutions. It is also consistent with our interpretation that *KSR* requires the number of options to be "small or easily traversed."

> Second, an invention is not obvious to try where vague prior art does not guide an inventor toward a particular solution. A finding of obviousness would not obtain where what was 'obvious to try' was to explore a new technology or general approach that seemed to be a promising field of experimentation, where the prior art gave only general guidance as to the particular form of the claimed invention or how to achieve it. This expresses the same idea as the *KSR* requirement that the identified solutions be 'predictable.'

Id. (citations omitted).

Sandoz has approached Merck's motion by arguing that the obviousness issue cannot be resolved on summary judgment because the parties' experts disagree, causing genuine material factual disputes to preclude the entry of judgment as a matter of law. The problem with this approach is that it is ill-suited to deal with situations like this one. Under Third Circuit law, "[a] nonmoving party has created a genuine issue of material fact if it has provided sufficient evidence to allow a jury to find in its favor at trial." Gleason, 243 F.3d at 138. Sandoz appears to have overlooked this principle, because it has not provided sufficient evidence to allow a jury to find in its favor at trial.

What is missing most conspicuously from Sandoz' briefing in opposition to this motion is evidence that the skilled artisan, at the beginning of the development process, would have viewed the final outcome of the process as one of a finite number of identified, predictable solutions. Sandoz offers a conclusory assertion from its expert on this point, but no evidence that provides a supporting foundation for that conclusion. Furthermore, Sandoz argues as if it is sufficient to show merely that the skilled artisan would have expected to succeed in developing some caspofungin formulation for intravenous administration. Of course, that is not legally sufficient to prove obviousness, since, under KSR, the question is whether the solution arrived at was one of a "finite number of identified, predictable solutions." 550 U.S. at 421. Sandoz tries to get

around this by pointing to the evidence that many of the steps in the development process were well-known. Such a strategy misses the point: at issue is whether the solution was identified, predictable, and within a finite number of such solutions.

Sandoz bears the burden of proof at trial of the affirmative defense of invalidity due to obviousness. Thus, the movant meets its initial burden at summary judgment by pointing to the absence of evidence to support Defendant's case. The burden then shifts to Sandoz to point to evidence of record sufficient to establish all the elements of its case.

This Court finds that the evidence of record does not suffice to establish Defendant's case that the patent at issue is invalid for obviousness. Sandoz filed a response to Merck's Statement of Facts which shows the following facts to be undisputed:

> 10. It took the inventors of the '300 patent about two years to develop a stable formulation of caspofungin acetate that could be sold and administered to patients. (Byrn Decl., Ex. A at ¶ 68; see also Leonard Decl., Ex. G at MRK_CANOI156152; Ex. H at MRK_CANOOOI9918.)
> Response: Agreed.
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> . . .
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> 12. The inventors discovered that a solution formulation approach was inadequate for long-term storage due to chemical degradation of caspofungin. (Leonard Decl., Ex. G at MRK_CANOI156155.) Sandoz has not provided any evidence that this was known in the prior art. (Leonard Decl., Ex. B at ¶¶ 28-29.)
> Response: Agreed.
>
> 13. The inventors learned during formulation development that caspofungin degrades by multiple chemical pathways, a fact not disclosed in the prior art. (Byrn Decl., Ex. A at ¶ 55.)
> Response: Agreed-in-part. The inventors learned during preformulation that caspofungin degrades by multiple chemical pathways, as would anyone else who was doing routine preformulation studies on caspofungin (Lemek Decl., Ex. 3, pp. 106-107).
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> 14. During formulation experimentation, the inventors attempted lyophilized

formulations of caspofungin acetate both with and without a citrate buffer and excipients. (Leonard Decl., Ex. W at MRK_CAN00897420, 425.) Both lyophilized formulations failed to stabilize caspofungin acetate. (Id.)
Response: Disagreed. Both formulations provided a stable formulation at 5°C, the same temperature at which Cancidas is stored (Leonard Decl., Ex. W at MRK_CAN00897425).

15. The inventors also attempted a lyophilized formulation of caspofungin with excipients and a tartrate buffer. (Leonard Decl., Ex. I at MRK_CAN00000629.)
Response: Agreed.

16. The tatrate-buffered attempt also failed, and led to the discovery of a new problem, namely the observation of a previously unknown degradant in unacceptable amounts. (Leonard Decl., Ex. J at 22; Ex. Kat 51:14-52:1, 212:14-20; see also Byrn Decl., Ex. A at ¶¶ 60-61.) The inventors referred to this degradant as "Degradate A" or L-717. (Leonard Decl., Ex. K at 51:14-52:1, 212:14-20; Ex. I at MRK_CAN00000621, 632.)
Response: Agreed.

17. Degradant L-717 was not known in the prior art, and created a new and unpredictable obstacle for the inventors. (See Leonard Decl, Ex. L; Ex. M; see also Byrn Decl., Ex. A at ¶¶ 60-61.) L-717 is not observed when caspofungin is alone as a solid or is in a solution formulation, and is only observed in lyophilized formulations. (See Byrn Decl., Ex. A at ¶¶ 60- 61.)
Response: Disagreed. Degradant L-717 was not a problem because it is not toxic (Lemek Decl., Ex. 3 at 109:1-4). Also, this would not have been a problem to a POSA who would have had no reason to use a tartrate buffer in the first place. (Leonard Decl., Ex. A at ¶ 69). Thus, this degradant was a problem of Merck's creation and unique to their poor choice of a buffer, rather than the problem a POSA was attempting to solve.

18. Sandoz has not alleged that a POSA would have predicted the occurrence of L-717 in lyophilized caspofungin formulations. (See, e.g., Leonard Decl., Ex. Cat 232:4-233:6.)
Response: Agreed.

19. Degradant L-717 presented a significant challenge for the Merck inventors, including identifying a mechanism for its formation. (Leonard Decl., Ex. K at 50:13-52:1, 187:11-25; see also Byrn Decl., Ex. A at ¶¶ 60-61.)
Response: Disagreed. Degradant L-717 was not a problem because it was not toxic (Lemek Decl., Ex. 3 at 109:1-4). Also, it would not have been discovered had the Merck inventors tried a logical buffer (e.g., acetate) in the first place. (Leonard Decl., Ex. A at ¶ 69).

20. The inventors initially attributed degradant L-717 to oxidation of caspofungin, a finding they later discovered was erroneous. (Leonard Decl., Ex. K at 51:20-52:1, 187:2-16.)
Response: Agreed.

21. The inventors unexpectedly discovered that using an acetate buffer in a caspofungin lyophilized formulation in place of a tartrate buffer significantly reduces the amount of degradation of caspofungin, including the amount of L-717. (Leonard Decl., Ex. K at 211:12-214:22; Ex. H at MRK_CAN00019918; Ex. I at MRK_CAN00000632, 636, 659; see also Byrn Decl., Ex. A at ¶ 90.)
Response: Disagreed. The use of an acetate buffer was not "discovered" by the inventors because acetate was one of the most common buffers and it was an obvious choice. (Lemek Decl., Ex. 11 at 1529; Ex. 2 at p. 194). The use of an acetate buffer was not "unexpected" because of its widespread use and success in other formulations and because there was no reason to believe that it would not work in a caspofungin formulation. (Leonard Decl., Ex. A at ¶¶ 94-99).

22. Merck scientists do not know why the acetate-buffered lyophilized caspofungin formulations are more stable than the corresponding tartrate-buffered ones. (Leonard Decl., Ex. K at 212:22-214:22.)
Response: Agreed.

23. Sandoz's sole formulation expert, Dr. Mark Staples, provides no explanation for acetate's superiority in caspofungin formulations, and admits that there could have been no way to predict acetate's superiority in lyophilized caspofungin formulations. (Leonard Decl., Ex. C at 223:4-224:4.)
Response: Disagreed. Dr. Staples explains that the successful use of acetate to buffer a caspofungin formulation was obvious and expected. Tests were required to confirm that fact, but the test results were not surprising. (Leonard Decl., Ex. A at ¶¶94-99). The only thing that was surprising was that Merck tried tartrate in the first place. (Id. at ¶69).

. . .

40. Dr. Staples admits that a POSA would first have prepared a solution formulation of caspofungin before even contemplating a lyophilized formulation: "[i]f an [intravenous] dosage form was the target product image, a POSA would have initially sought to develop a solution dosage form." (Leonard Decl., Ex. B at ¶ 20.)
Response: Agreed.

41. Dr. Staples asserts that a POSA would eventually move on to lyophilization only "if the solution development failed to produce acceptable quality product in

the required timeframe." (Leonard Decl., Ex. B at ¶ 29.) Dr. Staples never defines "acceptable quality" or quantifies the "required timeframe." (Id.)
Response: Agreed.

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56. Dr. Staples further admits that prior to adding a buffer to a formulation "you would first need data showing that there is, in fact, a pH drift [i.e., a showing that the pH of the solution changes over time]." (Leonard Decl., Ex. C at 202:2-13.)
Response: Agreed.

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64. Dr. Staples states that a POSA would select an acetate buffer for a lyophilized formulation of caspofungin because solution stability experiments conducted by the inventors showed the least amount of degradation was at pH of 5. (Leonard Decl., Ex. A at ¶ 84.) Sandoz does not allege, nor does it provide evidence, that this solution stability information was known in the prior art: (Id.) The drug shelf-life would be projected from the preformulation stability data at various pHs. A suitable buffer would be selected based in part on this data. For caspofungin, the solution stability would have revealed the optimal pH was 5.
Response: Agreed.

. . .

67. The acetate-buffered lyophilized formulations made by Merck scientists turned out to be most stable when the pre-lyophilized solution has a pH of 6. (Leonard Decl., Ex. C at 233:17-234: 18; Ex. I at MRK_CAN00000649; see also '300 patent, col. 3, ll. 14-17.)
Response: Agreed.

68. A pH of 6 is outside of acetate's normal buffering range. (See Leonard Decl., Ex. A at Exhibit B; Byrn Decl., Ex. A at ¶¶ 97-98.)
Response: Agreed.

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72. Dr. Staples concedes that in lyophilized formulations "what happens ... when you freeze dry a system is that certain portions of that mixture get extremely complicated during the drying process. Even though they're frozen and cold, things are still going on from a chemical and physical standpoint, and these are very hard to predict." (Leonard Decl., Ex. C at 232:4-233:6, emphasis added.)
Response: Agreed.

These statements of undisputed fact may be distilled into the following key points. It took two years of research and experimentation to develop the patented formulation. In this process, the patentee discovered a number of path-determinative facts: 1) the solution formulation approach was inadequate due to chemical degradation of caspofungin; 2) the approach of lyophilization with a tartrate buffer failed; 3) experimental evidence showing pH drift resulted in the search for a buffer; and 4) solution stability experiments demonstrated the least caspofungin degradation at a pH of 5, but the acetate-buffered formulations turned out to be most stable when the pre-lyophilized solution had a pH of 6, outside of acetate's normal buffering range.

For the sake of discussion, let us assume that Sandoz has presented the evidence necessary to persuade a finder of fact that its responses, cited above, are true. On this record, no reasonable finder of fact could make factual determinations that would support a conclusion of obviousness. Rather than showing that the development of the patented formulation was humdrum and routine, and that the formulation arrived at was one of a finite number of identified, predictable solutions, the evidence shows, certainly, that it was not predictable from the start.

The undisputed evidence thus shows that, while initial experiments predicted optimal stability at pH 5, the patented formulation has optimal stability at pH 6 – outside the normal buffering range for acetate. There is no dispute that the chemical stability of the formulation is a key characteristic of a useful pharmaceutical, nor that the patent claims require use of an acetate buffer. Sandoz does not explain how these results could possibly have been expected – since the undisputed evidence is that they are not what would have been expected. This alone precludes

proving obviousness.[3] Sandoz has offered no evidence that a skilled artisan would have had a reasonable expectation of success in using an acetate buffer outside of its normal buffering range.

There are quite a few more problems with Sandoz' case. Sandoz contends that the fact that the patentee experimented with a formulation using a tartrate buffer was a "poor choice" on the patentee's part. Sandoz is thus in the peculiar position of arguing that the patented formulation was obvious to one skilled in the art – and yet the patentee failed to see it and chased down a dead end first. This makes no sense.

Not only has Sandoz failed to offer evidence sufficient to prove its obviousness case, but the evidence that it has offered shows that this case falls within one or both of the categories of cases in which "obvious to try" does not prove obviousness: 1) where there are numerous possible solutions and the prior art gives no indication of which is likely to be successful, Bayer, 575 F.3d at 1347; and 2) "where what was 'obvious to try' was to explore a new technology or general approach that seemed to be a promising field of experimentation, where the prior art gave only general guidance as to the particular form of the claimed invention or how to achieve it." Id.

As the Federal Circuit has stated, the first of these situations is the inverse of the situation

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[3] In KSR, the Supreme Court illustrated the application of the doctrine that the "combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results" by discussing three cases. 550 U.S. at 416. In one of the three cases, Sakraida v. Ag Pro, Inc., 425 U.S. 273, 282 (1976), the Court held: "this patent simply arranges old elements with each performing the same function it had been known to perform . . .Such combinations are not patentable." In the instant case, in contrast, it cannot be maintained that one old element, the acetate buffer, performed the same function it had been known to perform. Rather, given that acetate has not been known to buffer optimally at pH 6, in the patent at issue, it performs differently from how it has been known to perform. This supports a conclusion of nonobviousness.

described by the Supreme Court as follows: "[w]hen there is a design need or market pressure to solve a problem and there are a finite number of identified, predictable solutions," KSR, 550 U.S. at 421. In such a situation, a finding of "obvious to try" might prove obviousness. Such is not the case here. No reasonable finder of fact could hear the evidence offered by Sandoz and conclude that the skilled artisan seeking to create a caspofungin formulation for intravenous use would have recognized the patented formulation as one of a finite number of identified, predictable solutions.[4] To the contrary, there is no evidence that the patented formulation was among a number of solutions that was finite, nor that it was predictable. The undisputed evidence is that lyophilization is a process that is, as Sandoz' expert admitted, "very hard to predict." (Leonard Decl., Ex. C at 232:18). Dr. Staples' deposition testimony on lyophilization is devastating to Sandoz' obviousness case:

> Because what happens when -- when you freeze dry a system is that certain portions of that mixture get extremely complicated during the drying process. Even though they're frozen and cold, things are still going on from a chemical and physical standpoint, and these are very hard to predict. If you're developing a freeze dried formulation, anyone of ordinary skill will understand that they -- they should base their experiment on observations they have made in the solution state as a starting point, but as a starting point only. And then they'll use that as an aid to design the freeze dried study but they -- I would not say they would feel they could predict anything. They would understand a standard way to design the experiment and to evaluate, but I don't believe they would claim that they could predict what would happen.

(Id. at 232:12-233:6.) Dr. Staples thus states unambiguously that the skilled artisan must experiment with freeze-drying and cannot predict the outcome of the experiments.[5] There is no

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[4] Nor has Sandoz presented evidence demonstrating that the number of possible solutions was "small or easily traversed." Bayer, 575 F.3d at 1347.

[5] Similarly, when asked about whether a skilled artisan could predict solution stability at various pH levels, Dr. Staples stated: "At this early stage, usually you don't -- you don't know

evidence of record to the contrary, and this stands as an undisputed fact. Sandoz cannot prove that this was a predictable solution, and thus cannot prove obviousness through this approach.

The evidence does show, rather, that this case fits within that class of cases in which it is error to find that "obvious to try" proves obviousness: where the prior art gives only general guidance to the form of the invention. This is a corollary to what has just been shown: the prior art did not allow the skilled artisan to identify a finite number of specific, predictable solutions. Instead, it offered only general guidance. The evidence of record suggests that the idea of creating a caspofungin formulation for intravenous administration through lyophilization was not more than a promising field of experimentation, and that the discovery of the patented formulation was not an obvious, particular solution.

A related inquiry is whether the skilled artisan would have had a reasonable expectation of success with the patented formulation. In In re O'Farrell, 853 F.2d 894, 903-904 (Fed. Cir. 1988), the Federal Circuit held: "Obviousness does not require absolute predictability of success. . . . For obviousness under § 103, all that is required is a reasonable expectation of success." The Federal Circuit reaffirmed the vitality of this principle after KSR in In re Kubin, 561 F.3d 1351, 1360 (Fed. Cir. 2009). Sandoz has failed to offer evidence from which a reasonable trier of fact could conclude that the skilled artisan, beginning the process of developing an intravenous formulation of caspofungin, would have had a reasonable expectation of success with the patented formulation. To the contrary, the undisputed evidence of record demonstrates that the

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enough about the system to go to the level of sophistication that you're suggesting in that type of prediction." (Leonard Decl., Ex. C at 231:24-232:3). There is no dispute that achieving maximum solution stability is a key part of the formulation process, and Dr. Staples is again here conceding that this cannot be predicted, but must be determined by experimentation.

skilled artisan in those circumstances would have been unable to predict the outcome of the experiments necessary to develop the formulation.

This conclusion is supported by the undisputed evidence that Merck scientists do not know why the acetate-buffered formulations are more stable that corresponding tartrate-buffered ones. This suggests that the success of this combination was not predictable, nor that there was a reasonable expectation of success in combining these elements.

Merck contends correctly that Dr. Staples' assertion in his expert report that the skilled artisan would have had an expectation with success with lyophilization is a purely conclusory assertion which should not be credited. As Merck observes, this conclusion is directly contradicted by Dr. Staples' deposition testimony, quoted above, that the skilled artisan would not be able to predict the results of lyophilization. This Court disregards the conclusory assertion contradicted by the record. See Shaw by Strain v. Strackhouse, 920 F.2d 1135, 1139 (3d Cir. 1990) ("To the extent that the affidavits assumed facts about this case unsupported by the record, however, the expert opinions were properly disregarded.")

Merck also notes that the evidence of record shows that, prior to the development process, the prior art contained no information about the stability of caspofungin or caspofungin formulations. Sandoz has pointed to no contrary evidence. In Defendant's Counter-Statement of Facts, there is a section with the heading, "Knowledge of Caspofungin at the Time of the Invention." (Def.'s 56.1 Counter-Statement 8.) No factual statements in this section assert any knowledge about the stability of caspofungin or caspofungin formulations. Rather, to the extent that the statements address this issue, they assert the absence of knowledge of the instability of caspofungin.

Sandoz thus takes the position that, prior to the process of developing the patented formulation, the skilled artisan had no knowledge about the stability of caspofungin or caspofungin formulations and that substantial problems with stability had to be dealt with and overcome during development, but that the solution to these problems that were previously unknown was an obvious one. This makes no sense and is entirely unpersuasive.

Plaintiff has moved for summary judgment on Defendant's affirmative defense to infringement of invalidity based on obviousness. Defendant bears the burden of proof of invalidity, by clear and convincing evidence, at trial. As the movant without the burden of proof at trial, Plaintiff satisifies its initial summary judgment burden by pointing to the absence of evidence to support Defendant's case. The burden then shifts to the nonmovant, who must point to evidence sufficient to establish all the elements of its defense. Here, Sandoz has failed to prove an essential element of its obviousness case – that the skilled artisan at the beginning of the development process would have recognized a finite number of identified, predictable solutions, of which the patented formulation was one. This constitutes a complete failure of proof, and entitles the movant to judgment as a matter of law. Plaintiff's motion for summary judgment will be granted.

CONCLUSION

Plaintiff has demonstrated, pursuant to Federal Rule of Civil Procedure 56, an absence of disputes over material facts, and has shown that it is entitled to judgment as a matter of law. Plaintiff's motion for summary judgment is granted, and as to Defendant's affirmative defense to infringement of patent invalidity due to obviousness, Judgment will be entered in favor of Plaintiff.

s/ Stanley R. Chesler
Stanley R. Chesler, U.S.D.J.

Dated: January 30, 2012